K080095

APR 11 2008

510 (k) Summary

Medinvents NV
510 (k) Premarket Notification for Coramate/Spirotome
K080095

Premarket Notification 510(k) Summary
(per 21 CFR 807.92)
Coramate/Spirotome System
Submitted by:
Magda Buttiens
CEO Medinvents
B-3500 Hasselt – Belgium

Phone: +3211271557
Fax: +3211283677
Email: magda.buttiens@medinvents.com

Date prepared: February 25, 2008
Device Name:
Trade Name: Coramate/Spirotome system
Classification Name: Biopsy Needle

Predicate Devices:

Organ	Predicate device	ID-PD	510 (k) application	Remarks
Skin	Punch Biopsy needle	K896303	Spirotome (Easy Punch)	
Vulva	Punch Biopsy needle	K896030	Spirotome (Easy Punch)	
Breast	Mammotome	K033700	Spirotome/Coramate	K060384
Lymph node	Tru-cut needle	K024120	Spirotome/Coramate	
Thyroid, salivary gland	Tru-cut needle	K024120	Spirotome/Coramate	
Salivary gland	Tru-cut needle	K024120	Spirotome/Coramate	
Liver	Tru-cut needle	K024120	Spirotome/Coramate	
Cervix	Forceps	K842112	Spirotome Cervicore	
Muscle	Tru-cut needle	K024120	Spirotome/Coramate	
Abdominal wall	Tru-cut needle	K024120	Spirotome/Coramate	
Thoracic wall	Tru-cut needle	K024120	Spirotome/Coramate	
Bone	Bone marrow biopsy needle	K001132	Spirotome Bone	

Device Description:
The Coramate/Spirotome system is a mechanical biopsy device to harvest soft tissues from the human body. The Coramate/Spirotome system consists of 2 major components: the set of needles (Spirotome) and a powered device that operates the needles (Coramate). The set of needles can be operated manually as well (single-use and reusable Spirotome). The needle set contains 3 needles that work in conjunction.

K080095

Intended Use

Device Name	Indications for Use
Coramate system	The Coramate system is a core soft tissue biopsy medical devices to be used in humans to take out adequate samples from superficial soft tissues as breast, lymph nodes, thyroid, muscles, abdominal wall, thoracic wall and parotis. The Coramate system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities. The Coramate system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.
Spirotome system	The Spirotome system is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of soft tissue from subdermal structures as breast, abdominal wall, thoracic wall, lymph nodes, thyroid, parotis, muscles and liver. The Spirotome system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities. The Spirotome system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.
Cervicore system	The Cervicore system is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue from the human cervix. The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities by inspection or colposcopy. The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.
Easy Punch Spirotome	The Easy Punch is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue from the skin. The Easy Punch is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities. The Easy Punch is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.
Spirotome Bone	The Spirotome Bone is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of soft tissue from bony structures. The Spirotome Bone is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Technological Characteristics

The Coramate/Spirotome system is identical to the currently marketed macrobiopsy systems (K060384). It contains a needle set and a hand held powered device based on the same concept. In addition, substantial equivalence is noted towards the intended use in other soft tissue systems of the human body.

The basic system is a radial cutting of a cutting cannula on a helicoidal shaped receiving element. This system can be operated manually, whereby the system is advanced by the aid of a trocar needle up to the diseased area. Combined, this needle set is called ***the Spirotome*** and can be delivered single-use or as a reusable device.

The Coramate is a powered device that operates the same needles automatically. The interface with the patient is the same both in the Coramate and Spirotome: i.e. the needle set. In addition, the Coramate includes a vacuum to the needles for maximal performance. The Coramate contains a combination of interfaces, motors and software in addition to a battery with loader. The interfaces fix the needle set into the device. The 4 small motors perform the necessary movements of the needles. The software guides the motors into smooth and ordered movements of the needles. The batteries power the device. Accessories may be added to the system: e.g. releasing element, spacer, protecting ring, and battery loader.

Performance data

Thorough ***preclinical testing*** was performed to ensure the device performs as intended. In particular most laboratory and preclinical testing was done on animal tissues to ensure maximum performance in the human situation.

Clinical testing indicates that all performance and safety aims are reached. Since the interface of the system is the same in the Spirotome compared to the Coramate, all the clinical evidence gained by the Spirotome is relevant to the Coramate. Most of the clinical work has been done in human breast tissues as has been published in international PEER reviewed Journals and Meetings. In addition, ***recent clinical evidence is added relating to the performance in various other soft tissues than the breast. In summary, all this clinical data indicate that the Coramate and Spirotome perform as intended, with aimed performance and maximal safety and similar to the 'Indications for Use' of the predicate device.*** In particular, no complication was noted up to now in the clinical tests and subsequent vigilance quality control follow-up.

The Spirotome and Coramate devices comply with the European Medical Device Directive 92/42/EEC and clearance was given for all soft tissues of the human body. All requested standard testing according to the claims made have been done.

Conclusion

Based upon the testing and comparison to the predicate devices, the intended use of the Coramate/Spirotome system in other soft tissues than the breast was substantially equivalent to the intended use of the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

MedInvents
% Mr. Jaak Janssens
Klein Hillststraat 5
Hasselt, Limburg
Belgium 3500

Re: K080095
Trade/Device Name: Coramate system
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: March 6, 2008
Received: March 17, 2008

Dear Mr. Janssens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080095

Page 1 of 5

Coramate needle

Indications for Use

510(k) Number (if known): K080095

Device Name:
Coramate system

Indications For Use:

The Coramate system is a core soft tissue biopsy medical devices to be used in humans to take out adequate samples from superficial soft tissues as breast, lymph nodes, thyroid, muscles, abdominal wall, thoracic wall and parotis.

The Coramate system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities.
The Coramate system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities.

An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient.

In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Prescription Use____X____ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Spirotome needle

Indications for Use

510(k) Number (if known): K080095

Device Name:
Spirotome system

Indications For Use:

The Spirotome system is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of soft tissue from subdermal structures as breast, abdominal wall, thoracic wall, lymph nodes, thyroid, parotis, muscles and liver.

The Spirotome system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities.
The Spirotome system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities.

An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient.

In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Prescription Use____X____ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K080095

Page 3 of 5

Cervicore needle

Indications for Use

510(k) Number (if known): K080095

Device Name:
Cervicore Spirotome

Indications For Use:

The Cervicore system is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue from the human cervix.

The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities by inspection or colposcopy.
The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities.

An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient.

In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Prescription Use____X____ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mam

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080095

Easy Punch

Indications for Use

510(k) Number (if known): K080095

Device Name:
Easy Punch Spirotome

Indications For Use:

The Easy Punch is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue from the skin.

The Easy Punch is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities.
The Easy Punch is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities.

An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient.

In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Prescription Use____X____ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080095

K080095

Page 5 of 85

Spirotome Bone

Indications for Use

510(k) Number (if known): K080095

Device Name:
Spirotome Bone

Indications For Use:

The Spirotome Bone is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of soft tissue from bony structures.

The Spirotome Bone is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities.

An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient.

In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.

Prescription Use____X____ AND/OR Over-The Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINU ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)